IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
Charleston Division

DEREK CLEMENTS, *et al.*,	)	
	)	
Plaintiffs	)	
	)	
v.	)	Civil Action No. 2:22-cv-02069-RMG
	)	
LLOYD J. AUSTIN, III, *et al.*,	)	
	)	
Defendants.	)	
	)	

PLAINTIFFS' SECOND MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs, by and through counsel, respectfully submit this memorandum of points and authorities in support of their Second Motion for a Preliminary Injunction and Temporary Restraining Order pursuant to Fed. R. Civ. P. 65 and LCvR 65.01.

Plaintiffs request this Honorable Court preliminarily enjoin Defendants Secretary Austin and Admiral Fagan from enforcing their unlawful COVID-19 vaccine mandates and from disciplining Plaintiffs on the basis of remaining unvaccinated; specifically, as of the date of this filing, all United States Coast Guard Academy ("USCGA") cadets have been ordered disenrolled from the Academy, and all United States Military Academy ("USMA") cadets have been directed not to attend classes while their disenrollments are being processed. Plaintiffs ask that the Court order the Army and Coast Guard to refrain from treating these cadets any differently than their unvaccinated counterparts (as is consistent with the recent Center for Disease Control

and Prevention ("CDC") guidance[1]) until this injunction is resolved, to prevent the cadets from being forced into an academically deficient status requiring their disenrollment regardless of this litigation's outcome.[2] [3] Plaintiffs further request this Court set an expedited oral hearing pursuant to LCvR 7.08 on the Preliminary Injunction.

I. INTRODUCTION

While Defendant Department of Defense ("DoD") has a long history of vaccinating United States service members, it does not have a long history of vaccinating or treating service members with unlicensed drugs and vaccines. This phenomenon is relatively recent—first occurring in the 30 years or so since the first Gulf War. The first Gulf War witnessed hundreds of thousands of US service members treated with experimental (so-called "investigational new drugs", or "INDs") medicines without their knowledge or informed consent.[4]

The mass inoculations of service members in Gulf War I were essentially undocumented, thereby making it impossible for individuals to receive corrective treatment for any IND-related injuries.[5] This resulted in widespread suspicion that the cocktail of licensed and unlicensed

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[1] Ctrs. For Disease Control & Prevention, CDC streamlines COVID-19 guidance to help the public better protect themselves and understand their risk, https://www.cdc.gov/media/releases/2022/p0811-covid-guidance.html (last visited Aug. 15, 2022).

[2] For example, preventing the Army from placing prohibitions on cadets against attending classes or performing other cadet duties consistent with their status.

[3] For example, preventing the Army from placing prohibitions on cadets against attending classes or performing other cadet duties consistent with their status.

[4] *See*, Gulf War and Health: Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, and Vaccines The National Academies Press (2000), available at https://www.ncbi.nlm.nih.gov/books/NBK222861/ (last visited

[5] *Id.*

medicines administered to service members caused long-term illnesses, the much discussed "Gulf War syndrome," in veterans of that conflict.[6]

In response to DoD's malfeasance, Congress enacted 10 U.S.C. § 1107, a statute that specifically prohibits the use of INDs on service members without their informed consent, or without a presidential waiver of that consent. These requirements were reinforced by Executive Order 13139, and DoD Directive 6200.2.[7]

Defendant DoD promptly validated Congress's concern about DoD's cavalier attitude towards the use of unlicensed drugs and vaccines by forcibly inoculating hundreds of thousands of service members with an unlicensed anthrax vaccine. Not until it was forced to do so by a federal court did DoD finally acknowledge that the vaccine was unlicensed and that its program violated the requirements of 10 U.S.C. § 1107.

In part as a response to the issues raised by the anthrax case, DoD and the Food and Drug Administration ("FDA") established a new category of drug for unlicensed, non-IND drugs: "emergency use authorization" ("EUA"). Congress dutifully passed a modification of 10 U.S.C. § 1107, codified at 10 U.S.C. § 1107a, again prohibiting the mandatory inoculation of service members using unlicensed, EUA vaccines on service members without a waiver of their informed consent. Yet once again, the government has proven totally unwilling to abide by the statutory requirements enacted by Congress to protect service members from becoming, as Judge

[6] See, *Id*., Chapter:7, https://doi.org/10.17226/9953; *Doe v. Rumsfeld*, 297 F.Supp.2d 119, 125 (D.D.C. 2003) (noting, e.g., that while initially the risk of serious adverse effects from taking the anthrax vaccine was considered to be low (0.2%), subsequent evaluations considerably raised the risk of adverse effects (to 5.0-35.0%)).

[7] *Id.*

Sullivan so eloquently stated in *Doe v. Rumsfeld*, "guinea pigs." *Doe v. Rumsfeld*, 297 F.Supp.2d at 134-35.

Against this backdrop, in 2003 service members challenged DoD's order to take the clearly experimental anthrax vaccine. On review, the court granted the plaintiffs' request for a preliminary injunction, finding that although DoD sought to protect its service members, for which the military is typically afforded a large amount of discretion, its anthrax vaccination order was in violation of the statutory requirements of 10 U.S.C. § 1107, requiring informed consent for experimental inoculations in the absence of a presidential waiver.[8] The court found that the plaintiffs met each factor, including that they were likely to succeed on the merits of their case, and granted their motion for a preliminary injunction.

This case parallels *Doe* in every critical aspect and demonstrates that DoD has failed or simply refuses to learn its lesson from the *Doe* case. It has once again ordered that its servicemembers submit to an inoculation with a vaccine that is unlicensed, this time in violation of 10 U.S.C. § 1107a.[9] Unfortunately for DoD, the rationale remains the same as it was in 2003. As the *Doe* court noted then, "the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld*, 297 F. Supp. 2d at 134

[8] The *Doe* court summarized the issue as such: "[p]ending before this Court is a Motion for a Preliminary Injunction. The central question before this Court is whether AVA is an "investigational" drug or a drug unapproved for its use against inhalation anthrax." *Doe*, 297 F. Supp. 2d at 123.

[9] Section 1107a was created by Congress and signed into law in part in response to the DoD's attempts to circumvent § 1107.

II. STATEMENT OF FACTS

In response to a novel virus first detected in 2019—now referred to as COVID-19—a Gadarene rush ensued to develop and produce equally novel vaccines. Am. Compl. at ¶ 38. The Pfizer-BioNTech vaccine, the Moderna vaccine, and the Johnson & Johnson Janssen vaccine were pressed into use in the United States under the auspices of the FDA's Emergency Use Authorization ("EUA") provision found at 21 U.S.C. § 360bbb-3.[10] *Id.* at ¶ 39. After the FDA's emergency authorization, the manufacturers continued their efforts using FDA's Biologics License Application ("BLA") process with the ultimate goal of getting approval for a licensed product.[11] *Id.* at ¶¶ 39-41.

On August 23, 2021, the FDA issued a BLA approval letter to BioNTech Manufacturing GmbH of Mainz, Germany, for one of its various formulas of the vaccine—BNT162b2.[12] *Id.* at ¶¶ 40-44. BioNTech, in conjunction with Pfizer, was permitted to label and market this licensed formula with the proprietary name "COMIRNATY."[13] *Id.*[14] Its distribution was prohibited until

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[10] *See* Ctrs. for Disease Control & Prevention, How CDC is Making COVID-19 Vaccine Recommendations (2019), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html#:~:text=%E2%80%A2%20On%20Dec.%2011,of%20COVID%2D19 (last visited Oct. 13, 2021) (the Pfizer-BioNTech COVID-19 vaccine received EUA on December 11, 2020; the Moderna COVID-19 vaccine received EUA on December 18, 2020; and the Johnson & Johnson Janssen COVID-19 vaccine received EUA on February 27, 2021).

[11] *See* U.S Food & Drug Admin., Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry (2020), https://www.fda.gov/media/139638/download (last visited June 24, 2022).

[12] U.S Food & Drug Admin, Pfizer-BioNTech COVID-19 EUA LOA reissued August 23, 2021, (Aug. 23, 2021), https://www.fda.gov/media/151710/download (last visited June 24, 2022).

[13] *Id.*

[14] *Id.*

the manufacturer submitted a final container sample of the product and received a notification of release from FDA's Director of the Center for Biologics Evaluation and Research.[15] At the time of the FDA's issuance of the license, COMIRNATY was not being manufactured in the United States, nor would it be for the foreseeable future.[16] *Id.* at ¶¶ 44-45.

When it issued the BLA approval letter, the FDA simultaneously notified Pfizer that the Pfizer-BioNTech vaccine EUA was being extended because "[t]here [was] no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine." *Id.* at ¶¶ 41-43. The FDA's letter noted that although the two products had similar chemical compositions, they were legally distinct and had "certain differences"—with "certain differences" remaining undefined.[17] *Id.* at ¶ 42.

On November 18, 2022, Pfizer-BioNTech requested to supplement its BLA with a different vaccine formula. *Id.* at ¶ 44. Less than one month later, this request was approved, and the FDA permitted Pfizer-BioNTech to distribute this version of COMIRNATY with a gray cap and label (the first version, never manufactured or distributed, was supposed to have a purple cap and label).[18] *Id.* Notwithstanding the supplemental approval, the FDA has continued to reissue

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[15] *Id.*

[16] *Id.*

[17] U.S. Food & Drug Admin, Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (Aug. 23, 2021), http://web.archive.org/web/20210823142928/https:/www.fda.gov/media/150386/download (last visited June 27, 2022).

[18] U.S. Food & Drug Admin., BioNTech BLA Supplemental Approval (Dec. 16, 2021), https://www.fda.gov/media/154939/download (last visited June 21, 2022).

the EUA for the Pfizer-BioNTech vaccine, with the latest EUA issued on June 17, 2022.[19] *Id.* at ¶ 42. In other words, as of June 2022, the FDA still maintained there was no "adequate, approved, and available alternative to this product." *Id.* Indeed, as of the initial filing of this case, on the FDA "Vaccine Finder" website, COMIRNATY was not available in the United States.[20] Recent attempts by multiple Plaintiffs only confirm this continued lack of availability. *See* Exhibits 1-7.

Further clouding its already bizarre licensing and EUA decisions, at the time it licensed COMIRNATY, FDA opined that COMIRNATY and the Pfizer-BioNTech COVID vaccines could be used "interchangeably" for treatment purposes.[21] *Id.* at ¶ 59-61. Notably, the FDA's Purple Book, which lists all regulatory aspects of a drug or vaccine's licensing and status, shows there is *no* vaccine that is interchangeable with COMIRNATY.[22] More importantly, the designation of a vaccine as being interchangeable with another vaccine cannot happen merely with the stroke of some bureaucrat's pen on FDA letterhead. "Interchangeability" has very specific requirements with respect to evaluation of the vaccines involved. *Id.* at ¶¶ 59-61. Not

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[19] U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (June 17, 2022), https://www.fda.gov/media/150386/download (last visited Jun. 21, 2022).

[20] *See* Ctrs. for Disease Control and Prevention, https://www.vaccines.gov/search/, (last visited June 27, 2022).

[21] U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (Aug. 23, 2021), http://web.archive.org/web/20210823142928/https:/www.fda.gov/media/150386/download (last visited June 27, 2022).

[22] *See Purple Book Database of Licensed Biological Products*, U.S. Food & Drug Admin., https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty (last visited June 24, 2022).

one of those requirements has been met with respect to either of these vaccines, and there is no legal basis for the FDA to make such a designation. *Id.*

This confusing licensing decision by FDA changed nothing about how vaccinations in the United States were administered, with one notable (and apparently deliberate) exception—it has been widely reported by the press and generally assumed by the public at large that the Pfizer-BioNTech vaccine administered for a year now is fully licensed by FDA. But it is not. Until recently, every vial of vaccine used in the United States (regardless of manufacturer) contains a label clearly stating that it is "For use under Emergency Use Authorization." *Id.* at ¶ 45.

On August 9, 2021, Defendant Secretary of Defense Austin issued a memorandum notifying the entire DoD that the President had asked him "to consider how and when [DoD] might add the coronavirus disease 2019 (COVID-19) vaccines to the list of those required for all Service members."[23] *Id.* at ¶ 46. Defendant Secretary of Defense Austin stated that he would mandate involuntary inoculation with a COVID-19 vaccine by either seeking the President's approval to use unlicensed, EUA vaccines no later than mid-September, or upon approval by the FDA, whichever occurred first.[24] *Id.*

Defendant Secretary of Defense Austin wasted no time in issuing the mandate once the FDA "licensed" COMIRNATY on August 23, 2021. The very next day, August 24, 2021, he mandated all service members receive "full vaccination" against COVID-19, using only fully

[23] Sec'y of Def., Memorandum For All Department Of Defense Employees (Aug. 9, 2021), https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF (last visited June 21, 2022).

[24] *Id.*

licensed vaccines. [25] *Id.* at ¶ 47. The various services and academies, including the United States Coast Guard and USCGA, began to carry out the mandate faithfully.[26] Per Defendant Secretary of Defense Austin, Service members with prior COVID-19 infection would not be considered fully vaccinated.[27] *Id.* at ¶¶ 47-48.

Each of the armed services and the Coast Guard issued implementation guidance that requires either individual compliance with Defendant Austin's order or disciplinary action, including involuntary separation from the service. *Id.* at ¶¶ 47-50.

Consequently, because they object to taking the vaccine, Plaintiffs are being subjected to disciplinary action, including threats of separation and active steps toward disenrollment from the academies. *Id.* at ¶¶ 1-29, 66. Numerous Plaintiffs have received Letters of Reprimand, and the USCGA and USMA cadets have already been served their disenrollment orders. *Id.* at ¶¶ 25-29.

Because the vaccines currently available in the United States remain under EUA, Plaintiffs are required to be vaccinated with unlicensed vaccines. The requirements for

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[25] Sec'y of Def., Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members (Aug. 24, 2021), https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited June 21, 2022).

[26] Then-Commandant of the Coast Guard Admiral Schultz issued a Coast Guard order on August 26, 2021, wholly adopting Defendant Secretary of Defense's August 24 memorandum. *See* ALCOAST 305/21 (Aug. 26, 2021).

[27] Sec'y of Def., Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members, (Aug. 24, 2021), https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited June 21, 2022).

deployment of an EUA drug or biologic are laid out in 21 U.S.C. § 360bbb-3 of the Food, Drug, and Cosmetics Act ("FDCA"). In addition, there are specific requirements that apply to the use of an EUA vaccine on service members. *See* 10 U.S.C. § 1107a. In short, that statute prohibits the use of an EUA vaccine as part of a mandatory vaccination program for service members without either the service member's informed consent—without consequence for refusal—or a presidential waiver of the informed consent requirement. From the very inception of this ill-conceived vaccine mandate, Defendant willfully ignored the requirements of 10 U.S.C. § 1107a. Compl. at ¶¶ 46-52; *Cf.*, *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004).

In addition to the requirements attached to EUA vaccines, Defendants have also circumvented regulations that require evaluation of a service member's natural immunity derived from previous infection. *See* Army Regulation 40-562, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (Oct. 7, 2013) ("AR 40-562") ("Medical commanders, commanding officers, and command surgeons: Ensure patients are evaluated for preexisiting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications."); Am. Compl. at ¶¶ 51-53.[28] This regulation, applicable to each of the Services, has been directly contravened,

[28] AR 40-562 at ¶1-1; ¶1-4.*c.*(4) ("Medical commanders, commanding officers, and command surgeons: Ensure patients are evaluated for preexisiting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications."); 2-6.*a.*(1)(*b*) (a medical exemption is warranted with "[e]vidence of immunity based on serologic tests, documented infection, or similar circumstances."); 3-1.*a.*(2) "(Immunize if the primary series is incomplete, if a booster immunization is needed, or if the Service personnel has no serologic or documented evidence of immunity."); 3-1.*a.*(3) ("Before immunizing, conduct serologic testing where available."); and 3.1.*e.* ("Upon accession, screen commissioned and warrant officers for immunization *or immunity status* and vaccinate as required.").

because the services have not conducted any sort of analysis or evaluation of Plaintiffs' natural immunity to COVID-19. Indeed, Cadet N. Aime, Cadet T. Aime, Lt Col Babcock, Maj Baumann, Cadet Beggs, TSgt Carey, Cadet Cass, Cadet Conklin, Cadet Ford, Cadet Galdamez, Cadet D. Johnson, SrA Kloster, Cadet Mell, Cadet Morrison, Cadet Paul, Capt Pokrant, Cadet Pym, Cadet Shaffer, Cadet Staiger, Cadet Suess, SrA Vasiliu, and Cadet Wojtkow all have natural immunity, as confirmed by previous infection and/or positive antibody tests. Am. Compl. at ¶¶ 2-7, 10-18, 20-21, 24-28.

The service members and cadets are facing a Hobson's Choice of either being victimized by an illegal program that requires them to be injected with an unlicensed vaccine (that comes with its own set of risks and uncertainties) or be disciplined and face the loss of their professional careers because of their refusal to be inoculated. Litigation will be lengthy; absent preliminary injunction by this Court, the Coast Guard and Army cadets face certain disenrollment.

III. ARGUMENT

The undisputed facts before the Court, even at this early stage, demonstrate that Plaintiffs are likely to succeed in this litigation and are sufficient to sustain a preliminary injunction. The details of this mandatory vaccination program reveal direct and straightforward violations of laws designed to protect service members from forced submission to experimental vaccines.

The program runs roughshod over rights enshrined in regulations governing vaccination and inoculation of service members, namely the right to refuse inoculation with an unlicensed vaccine and the need to evaluate previous infection and individualized medical circumstances. Plaintiffs are currently being irreparably harmed by Defendants and their subordinate services' swift efforts to discipline, separate, and disenroll them, and Plaintiffs face further irreparable

damage in the immediate future if this program is not stopped. Injunctive relief is the only way to prevent further harm to their interests.

A. Standard of review for motions for preliminary injunctive relief.

This Court may issue preliminary injunctive relief when the movant demonstrates the following:

> (1) they are likely to succeed on the merits, (2) they are likely to suffer irreparable harm, (3) the balance of hardships tips in their favor, and (4) the injunction is in the public interest.

Pashby v. Delia, 709 F.3d 307, 320–21 (4th Cir. 2013) (citing *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365 (2008)). "[C]ourts considering whether to impose preliminary injunctions must separately consider each Winter factor." *Id.* (citing *The Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 347 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310, 130 S.Ct. 876 (2010), *aff'd*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (per curiam)). Nonetheless, courts can assign different weight to these factors, and a strong showing in one factor may be used in evaluating the others. *See id.* at 330 (finding that the likelihood of success undoubtably contributed to whether the injunction is in the public interest and noting that likelihood of success could satisfy the public interest factors). Any injunction that a court issues must be carefully circumscribed and tailored to remedy the harm shown. *See* Fed. R. Civ. P. 65(d); *Pashby*, 709 F.3d at 331 (citing *Schmidt v. Lessard*, 414 U.S. 473, 476, 94 S.Ct. 713 (1974)).

B. The undisputed facts show that Plaintiffs are likely to succeed on their APA claims because the services' enforcement of the DoD Vaccine Mandate violates 10 U.S.C. § 1107a, and DoD's own regulations

The vaccine mandate issued by DoD contravenes federal statutes and DoD regulations. These violations are properly addressed under the framework established by the Administrative Procedures Act, 5 U.S.C. § 702.

The APA permits Federal District Courts to hold unlawful and set aside agency action, findings, and conclusions found to be—

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> (B) contrary to constitutional right, power, privilege, or immunity;
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> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;

5 U.S.C. § 702.

The Federal District Courts have authority to review final agency actions under the APA. *Id.* A military action is justiciable when: (1) the action violates a constitutional right or the military has acted in violation of applicable statutes or its own regulations; and (2) the plaintiff has exhausted all available intraservice corrective measures. *Roe v. Dep't of Defense*, 947 F.3d 207, 218 (4th Cir. 2020). The exhaustion requirement is not absolute, though. Such exhaustion need not include an appeal to the Service's board for correction of military records, when the boards themselves are unable to adjudicate claims regarding the unlawful or unconstitutional nature of a military regulation, and there is no categorical requirement in this circuit that constitutional and facial claims be administratively exhausted prior to judicial review. *Roe v. Shanahan*, 359 F. Supp. 3d 382, 403 (E.D. Va. 2019) (referencing *Nationsbank Corp. v. Herman*, 174 F.3d 424, 429 (4th Cir. 1999)). Furthermore, exhaustion is unnecessary when it would be futile. *Id.* (quoting *McDonald v. Centra, Inc.*, 946 F.2d 1059, 1063 (4th Cir. 1991); *see*

also Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 12-13, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000) ("Doctrines of 'ripeness' and 'exhaustion' contain exceptions, however, which exceptions permit early review when, for example, the legal question is fit for resolution and delay means hardship, ... or when exhaustion would prove futile" (internal quotation marks and citations omitted)).

The APA mandates that "[a] court *must* set aside agency action it finds to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Marshall v. Purcell*, Civil No. 2:12–84–RMG–BHH, 2012 WL 613819, at *2 (D.S.C. Nov. 6, 2012) (quoting 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001)) (emphasis added); *see also Roe v. Dep't of Defense*, 947 F.3d 207, 218-220 (4th Cir. 2020) (noting the application of the APA to the military).

1. Plaintiffs have exhausted their administrative remedies, and to the extent any further administrative remedies exist, exhaustion would be unnecessary or futile.

Plaintiffs' challenges in this case center on the lawfulness of the DoD mandate as it was purposefully enacted in violation of statute and regulation. Each Plaintiff is a service member or cadet who is in the process of receiving discipline for not taking the vaccine. To that end, further exhaustion is futile. And, if Plaintiffs were to then appeal to their respective service's board for correction of military records, the very individual who set in motion the guidance on denying the religious accommodations—the Service Secretary—would be the one subsequently denying any such correction board decision. *See Roe*, 359 F. Supp. 3d at 403-04 (finding an appeal to the Air Force Board of Correction of Military Records futile when the same individual who made the decision to separate the plaintiffs from the Air Force in the first instance, would be the same decision maker on the Board's decision on any subsequent appeal).

With respect to the mandates being issued in direct violation of statute and service regulations, there is no adequate relief available through the Services' correction boards. The vaccine mandate was issued in violation of 10 U.S.C. § 1107a—knowing there were no FDA licensed vaccines available in the United States—and AR 40-562—disregarding immunity from prior infections. But as recognized in *Roe*, the correction boards "cannot adjudicate a claim that the [military's] policies and regulations themselves are unconstitutional or otherwise unlawful." *Roe*, 359 F. Supp. 3d at 403 (emphasis in original). With no automatic requirement for administrative exhaustion of such claims, this Court—like the *Roe* court—should also find Plaintiffs' challenge to the lawfulness of the mandate, absent further appeal to the correction boards, justiciable.

2. The DoD and Coast Guard mandates violate federal statute and service regulations by not following vaccination consent requirements.

Plaintiffs will also likely succeed in showing that Defendants' mandates were issued in violation of 10 U.S.C. § 1107a and DoD Instruction (DoDI) 6200.02, as the mandates require their respective military personnel to submit to an unlicensed vaccine without providing personnel the opportunity to refuse without consequence.

The DoD may only override service members' informed consent rights if it complies with the requirements of 10 U.S.C. § 1107a (the applicable statute for EUA products). *See* DoD Instruction (DoDI) 6200.02 at ¶¶ 5.2.2, 5.2.3. 10 U.S.C. § 1107a stipulates that "In the case of the administration of a product authorized for emergency use […] to members of the armed forces, the condition […] designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President

determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1).

At the time of the DoD mandatory vaccination memorandum, President Biden had not issued any such order authorizing the waiver of consent requirements necessary for EUA vaccines. Nor has he issued any such order at the time of this case's filing.

Not one single vaccine available in the United States at the time of the DoD's mandate was FDA-licensed.[29] At the time the order was issued (and as is overwhelmingly still the case), only EUA vaccines were available in any identifiable quantity in the United States. In fact, both DoD and various service branches were acutely aware of this complete lack of licensed vaccine stock, going so far as to direct personnel to order nominal amounts of FDA-licensed COMIRNATY vaccine once available in an attempt to avoid liability and to disguise the fact that the vaccines available in the United States (and thus to service members) were not FDA-licensed. Notably, despite their requests, Plaintiffs have not been offered a licensed vaccine. *See* Exhibits 1-7 (detailing lack of Comirnaty availability at the USAFA, USCGA, JB Charleston, Maxwell AFB, and Fairchild AFB).

By requiring each service member or cadet to receive an unlicensed vaccine that has been authorized for emergency use only, the mandates simply bypassed this critical statutory and regulatory requirement. *See* 10 U.S.C. § 1107a; DoDI 6200.02 at ¶¶ 5.2.2, 5.2.3.

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[29] Notably, the FDA's grant of an EUA is also subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the product." FDCA § 564(e)(1)(A)(ii)(III); 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). In granting each of the three COVID-19 vaccines their respective EUA status, the FDA included a consent condition as described in Section 564(e)(1)(A)(ii)(III), requiring that the FDA's "Fact Sheet for Recipients and Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet stipulates that it is each recipient's choice whether to receive the vaccine or not.

Defendants' actions will not survive the arbitrary and capricious review, which looks to Defendants' decision-making process at the time action was taken. The Court's arbitrary and capricious standard of review, while narrow, "does not reduce judicial review to a rubber stamp of agency action." *Ergo-W. Va., Inc. v. EPA*, 896 F.3d 600, 609 (4th Cir. 2018). In order to survive this review, Defendants "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Sierra Club v. Dep't of the Interior*, 899 F.3d 260, 293 (4th Cir. 2018) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Agency action is arbitrary and capricious when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

In conducting this review, the Court must "consider the record made before the agency at the time the agency acted," so "post-hoc rationalizations … have 'traditionally been found to be an inadequate basis for review.'" *Dow AgroSciences LLC v. Nat'l Marine Fisheries Srv.*, 707 F.3d 462, 467-68 (4th Cir. 2013). Further, the Court may not supply a reasoned basis for the agency's actions that the agency itself did not consider. *Bowman v. Transp., Inc. v. Arkansas-Best Freight Sys., Inc.,* 419 U.S. 281, 285-86 (1974).

In issuing a mandate to receive a federally licensed vaccine, knowing full well no such vaccine existed—nor would it exist—and, without seeking the President's written approval to use an EUA vaccine—as Defendant Secretary of Defense Austin was required to do per his own service regulation and federal law—Defendants have acted in a manner that belies statutory and

regulatory requirements, and therefore, his actions are unequivocally arbitrary and capricious. And, to date, Defendants' mandate remains in violation of statute and regulation. As such, Plaintiffs' case is clearly likely to be successful, thereby providing this honorable Court another basis for finding that a preliminary injunction is appropriate and warranted.

3. DoD's mandate contravenes regulations that require vaccination and inoculation programs take into consideration an individual's previous infection.

Plaintiffs can also show a likelihood of success in showing an APA violation of Defendants' own promulgated regulations, not just federal statutes. Defendants' regulations, as well as their subordinate Services' regulations (including AR 40-562), stipulate that vaccination cannot occur without proper consideration being given on a person-to-person basis, as determined by each individual's own medical circumstances and condition.

Defendants issued an order to all military personnel, mandating that all personnel should receive the COVID-19 vaccination. These orders purposefully excluded consideration of natural immunity. This purposeful exclusion is a direct afront to Defendants' own regulations and fails to account for the fact that a substantial number of Plaintiffs in this case retain natural immunity after previously contracting a COVID-19 infection. This includes Plaintiffs who were infected by COVID-19 in early 2021, and who still possess positive antibodies when tested in 2022.

This Circuit has never had reservations about "directing the military to comply with its own regulations where it has been shown that a regulation was not followed, and there has been a prima facie showing that a member of the military has been prejudiced thereby," to include cases of medical compliance. *Bluth v. Laird*, 435 F.2d 1065, 1071 (4th Cir. 1970); *see also Roe*, 947 F.3d at 218-220 (finding that individualized assessment was required in discharging servicemembers who were HIV positive); *United States ex rel. Brooks v. Clifford*, 409 F.2d 700

(4th Cir. 1969). "[W]hen the sovereign has established rules to govern its own conduct it will be held to the self-imposed limitations on its own authority, departure from which denies procedural due process of law." *Bluth*, 435 F.2d at 1071 (citing *United States v. Heffner*, 420 F.2d 809 (4th Cir. 1969)). "[I]n exercising its discretion, the military *will* be held to the positive commands it has imposed on itself as to what procedures and steps are to be followed in exercising its discretion." *Id.* (emphasis added).

As early as June 2021, Defendant DoD and its subordinates recognized that their own regulations required consideration of one's natural and prior immunity before requiring involuntary inoculation. For instance, the Army's Director of Healthcare Operations, Colonel ("COL") Dubray Kinney, Sr., and the Army Medical Command's Deputy Chief of Staff overseeing planning and operations, Brigadier General Wendy Harter, authored an information paper titled, "Vaccine Refusal and Exemption Procedures."[30] In this paper, COL Kinney summarized AR 40-562, and noted that general medical exemptions from the vaccine mandate included evidence of natural immunity.[31] And yet, just two short months later, this regulatory requirement was summarily disregarded.

Defendants are obligated to follow its own regulations, and in cases where it refuses to, this Court has authority to direct compliance. Accordingly, given Defendant's DoD straightforward violation of its own regulations requiring testing for natural immunity prior to involuntary inoculation, Plaintiffs will have no difficulty in proving its case on this point.

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[30] Davis Winkie, *Here's the Army rule for vaccine refusals, which service leaders brushed up on this summer*, Army Times (Aug. 25, 2021), https://www.armytimes.com/news/pentagon-congress/2021/08/25/heres-the-army-rule-for-vaccine-refusals-which-service-leaders-brushed-up-on-this-summer/.

[31] *Id.*

C. The unusual circumstances of these mandates will, by their very nature, create irreparable harm.

In addition to demonstrating likelihood of success, Plaintiffs need also establish that they are subject to irreparable harm absent a preliminary injunction. The irreparable harm typically needs to be of such imminence that there is a clear and present need for equitable relief—in other words, later action or monetary award will not suffice. *See Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017); *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 693 (4th Cir. 1994).[32]

"[A] deprivation of a constitutional right, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Miranda v. Garland*, 34 F.4th 338, 365 (4th Cir. 2022) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). A critical constitutional right is at play in this case: Plaintiffs' Fifth Amendment right to procedural due process is being violated by the mandates.

This Circuit has long held that when the military violates its own regulations, the aggrieved service member is denied procedural due process. *Bluth*, 435 F.2d at 1071. The Supreme Court has further clarified that the "Due Process Clause is implicated [when] an individual has reasonably relied on agency regulations promulgated for his guidance or benefit and has suffered substantially because of their violation by the agency." *United States v. Caceres*, 440 U.S. 741, 752-53 (1979). In addition to refusing the vaccine on religious grounds, many of the Plaintiffs in this case have continued refusal because they have acquired natural

[32] Notably, preliminary injunctions on behalf of military personnel against the military have long been established. *See Yahr v. Resor*, 431 F.2d 690, 690 (4th Cir. 1970).

immunity, and they stand firm that Defendants' regulations must afford them relief from involuntary receipt of the COVID-19 vaccine because of this natural immunity. Additionally, and despite Defendants' conflation and obfuscation efforts, the mandated vaccines are not licensed (and are still EUA vaccines), nor has there been the requisite Presidential waiver required by DoDI 6200.02 (and 10 U.S.C. § 1107a), meaning that Defendants are violating regulatory and statutory protections which require that Plaintiffs be presented the choice to provide or withhold informed consent. Their reliance on Defendants' own regulations is now to their own detriment and harm, as each one of these Plaintiffs faces involuntary separation from the service.

In short, Defendants' violations of Plaintiffs' Fifth Amendment rights constitute per se irreparable harm, which more than satisfies the irreparable harm factor needed to grant a preliminary injunction. Accordingly, Plaintiffs ask that this Honorable Court follow the growing number of federal courts that have analyzed the very same kind of violations, and grant Plaintiffs' motion for a preliminary injunction.

D. An injunction is in the best interest of Defendants, Plaintiffs, and the public, as it upholds the rule of law.

After establishing a likelihood of success and the likelihood of harm, Plaintiffs must also demonstrate that a preliminary injunction is in the best interests of the public. Here, Plaintiffs can demonstrate that such injunction is clearly in the best interests of the public, given the likelihood of success, the need to ensure regulatory propriety, and the need to retain trained and qualified service members and cadets at their posts.

First, Plaintiffs likelihood of success, as established in the preceding sections of this memorandum, is a factor that substantially weighs in favor of finding that the public's best

interests will be served by granting this preliminary injunction. *See Pashby*, 709 F.3d at 320–21; *The Real Truth About Obama*, 575 F.3d at 347 (overturned on other grounds).

Second, the preservation of regulatory propriety is of considerable public interest. To this point, in cases involving an injunction against a mandatory vaccine program in the military, federal courts have previously held that, "[T]he right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld*, 297 F. Supp. 2d at 134. As in *Doe*, Plaintiffs note that the best interests of the DoD, military, and Plaintiffs coincide in having government follow the law. Indeed, this is all that Plaintiffs seek in this injunction.

Third, the vaccine mandate and implementing orders would remove qualified service members from their posts, based on a distinction that is not relevant to the current state of COVID-19. Indeed, CDC guidance as of August 11, 2022, now states that there is no need to treat the vaccinated any differently from the unvaccinated. *See CDC streamlines COVID-19 guidance to help the public better protect themselves and understand their risk,* (Aug. 11, 2022) https://www.cdc.gov/media/releases/2022/p0811-covid-guidance.html (specifically providing guidance "regardless of vaccination status"). Without an injunction, these illegal orders will still be used to remove valuable assets from their posts before Plaintiffs can fully litigate and demonstrate the arbitrary, capricious, and unsupported nature of the orders. This would create considerable economic and institutional waste for the American taxpayer in the form of sunk training costs, sunk educational costs, and losing decades upon decades of invaluable institutional experience. For these reasons, this Court should find this factor in favor of Plaintiffs and grant the requested preliminary injunction.

E. The requested injunctive relief is tailored to the injury.

Finally, Plaintiffs can satisfy that the requested relief is tailored to the injury addressed above. *See Di Biase*, 872 F.3d at 231; *Pashby*, 709 F.3d at 319. All Plaintiffs ask for in this motion is to return the relationships between Defendants and Plaintiffs to the status quo ante, before the implementation of the unlawful vaccine mandate and subsequent implementation orders. *Id.* The injunctive relief does not seek to undo any actions already undertaken by the parties, but rather stops the implementation of the orders to prevent further violations of federal law and service regulations.[33] The requests are limited and reasonably related to correct APA violations detailed above.[34]

IV. CONCLUSION

For these reasons, Plaintiffs request this Honorable Court grant the aforementioned temporary restraining order and preliminarily enjoin Defendants from enforcing their unlawful

[33] Alternatively, should any Plaintiffs be disenrolled or separated prior to a decision on this motion, this Court does in fact have the authority to issue a restorative preliminary injunction. *See Di Biase*, 872 F.3d at 231 ("But a preliminary injunction can also act to restore, rather than merely preserve, the status quo, even when the nonmoving party has disturbed it") (citing *Aggarao v. MOL Ship Management Co., Ltd.*, 675 F.3d 355, 378 (4th Cir. 2012)); *see also Savoie v. Merchants Bank*, 84 F.3d 52, 59 (2d Cir. 1996). The reach of this restorative injunctive authority would inherently extend to the military, as while there are only a few limited areas in which a court can order injunctive relief against the military, restoring a service member to their previous position following the improper application of separation procedures is squarely within the court's authority and discretion. *See, e.g., Hoskins v. United States*, 40 Fed. Cl. 259 (1998); *Poole v. Rouke*, 779 F. Supp. 1546 (E.D. Cal. 1991).

[34] It should be noted that tailored relief may permissibly extend to non-Plaintiffs. *See Evans v. Harnett County Bd. of Educ.*, 684 F.2d 304 (4th Cir. 1982); *see also Lujan v. National Wildlife Federation*, 497 U.S. 871, 913, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990) (implying agreement); *National Mining Ass'n, et. al., v. U.S. Army Corps of Engineers, et. al.*, 145 F.3d 1399 (D.C. Cir. 1998); *Bresgal v. Brock*, 843 F.2d 1163 (9th Cir.1987); *Meyer v. Brown & Root Construction Co.*, 661 F.2d 369 (5th Cir. 1981).

orders and taking any adverse action against Plaintiffs for failing to obtain the vaccine pending final resolution of this case.

Respectfully submitted,

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